**Appendix 1. Study protocol: The emergency paediatric surgical airway- a systematic review of the literature** (as per **PRISMA-P**).1

Systematic review of the literature regarding theemergency paediatric surgical airway. This review is not an update and the protocol will not be registered.

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Contributions: LK and DJ will perform search. LK, DJ, MFS, BP will perform data synthesis and write the article.

Amendments: important protocol amendments will be documented.

Support: This study will receive no financial support. The sponsor of this study is the Academic Medical Centre, Amsterdam.

**Introduction:**

Rationale: Although an emergency surgical airway is recommended in the guidelines for a paediatric can’t intubate, can’t oxygenate, there is currently no evidence regarding the best technique for this procedure.

Objective: This study reviewed the available literature on the emergency surgical airway in order to give recommendations for establishing a best practice for this procedure.

**Methods:**

Eligibility criteria: Studies matiching the following criteria will be included in this systematic review. Study design: both Randomized Control Trials and Non-Randomized Interventional studies will be included. Randomized Control Trials offer the strongest evidence. However given the nature of the intervention we will also include non-randomized interventional studies as we consider the a-priori likelihood of a high number of RCTs on this subject to be limited. Patients: children 0 to 8 years or suitable animal/artificial models. In difficult airway algorithms and courses usually the age of 8 is used as a cut off for a different technique for a surgical airway for children and adults. Given the nature of the intervention we do not expect to find many studies that include children, therefore studies describing original data from animal or interventional models will also be included. Intervention: Emergency paediatric surgical airway technique Comparison: (other) Emergency paediatric surgical airway technique, not mandatory, case series single intervention is also acceptable. Outcome: time to tracheal access (defined as visual confirmation or presence of end tidal CO2) and/or time to reported effective oxygenation or ventilation, Success rate, Complications and/or Perceived ease of use of the technique.

Information sources: MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Science, Cochrane Central Register of Controlled Trials (CENTRAL), Google Scholar and LILACS databases will be searched with help of a clinical librarian at the author’s institution. Additional literature was sought through hand searching via references of relevant articles, journals and authors known to be expert in the field, to identify further studies.

Search strategy (Medline and Embase): Original search will be performed 21-10-2014. Additional search was performed 19-4-2017.

**MEDLINE(R)**1946 to Present
Search Strategy:

|  |  |
| --- | --- |
| **#** | **Searches** |
| 1 | exp \*airway management/ or exp \*intubation, intratracheal/ or exp \*respiration, artificial/ or \*tracheostomy/ or \*Airway Obstruction/ or \*Respiratory Insufficiency/ or (airway management or airway obstruction or difficult airway).ti,ab,kw. |
| 2 | (((pediatric\* or paediatric\* or child\*) adj3 surg\*) and (airway or ventilat\* or intubat\*)).ti,ab,kw. |
| 3 | ((pediatric\* or paediatric\* or child\*) adj3 (tracheostomy or cricothyreodotomy)).ti,ab,kw. |
| 4 | 1 or 2 or 3 |
| 5 | child/ or child, preschool/ or infant/ or infant, newborn/ or exp Pediatrics/ or (child or children or pediatric\* or paediatric\* or infant\* or newborn\*).ti,ab,kw. |
| 6 | surgery.fs. or (surgery or surgical or tracheotomy).ti,ab,kw. or exp Anesthesia/ or (anaesth\* or anesth\*).ti,ab,kw. |
| 7 | exp emergency treatment/ or exp Resuscitation/ or (emergen\* or problem\* or trauma or acute or life-threatening or complication\*).ti,ab,kw. |
| 8 | 4 and 5 and 6 and 7 |

("Airway Management"[MAJR] OR "Intubation, Intratracheal"[MAJR] OR "Respiratory Insufficiency"[MAJR] OR "Tracheostomy"[MAJR] OR airway management[tiab] or airway obstruction[tiab] or difficult airway[tiab]) AND ("surgery" [Subheading] OR surgery[tiab] or surgical[tiab] OR anaesth\*[tiab] or anesth\*[tiab] OR cricothyreotomy[tiab] OR trach\*[tiab]) AND ("Emergency Treatment"[Mesh] OR "Resuscitation"[Mesh] OR emergen\*[tiab] OR problem\*[tiab] OR  trauma[tiab] OR acute[tiab] OR life-threatening[tiab] OR  complication\*[tiab]) AND ("Child"[Mesh] OR "Pediatrics"[Mesh] OR "Infant"[Mesh] OR child[tiab] OR children[tiab] OR pediatric\*[tiab] OR paediatric\*[tiab] OR infan\*[tiab] OR neonate\*[tiab])

((("Airway Management"[Mesh]) AND "Pediatrics"[Mesh]) AND "Infant"[Mesh]) AND "Infant, Newborn"[Mesh] AND surgical airway

systematic[sb] AND (("Airway Management"[MAJR] OR "Intubation, Intratracheal"[MAJR] OR airway management[tiab] or airway obstruction[tiab] or difficult airway[tiab]) AND Pediatric)

author: Engelhardt T, Weiss M

Database(s): **Embase Classic+Embase**1947 to Present
Search Strategy:

|  |  |
| --- | --- |
| **#** | **Searches** |
| 1 | \*respiration control/ or endotracheal intubation/ or \*respiratory tract intubation/ or \*artificial ventilation/ or \*airway obstruction/ or exp \*respiratory failure/ or \*tracheostomy/ or \*tracheotomy/ |
| 2 | (airway management or airway obstruction or difficult airway).ti,ab,kw. |
| 3 | (((pediatric\* or paediatric\* or child\*) adj3 surg\*) and (airway or ventilat\* or intubat\*)).ti,ab,kw. |
| 4 | ((pediatric\* or paediatric\* or child\*) adj3 (tracheostomy or cricothyreotomy)).ti,ab,kw. |
| 5 | 1 or 2 or 3 or 4 |
| 6 | child/ or preschool child/ or infant/ or newborn/ or pediatrics/ or (child or children or pediatric\* or paediatric\* or infant\* or newborn\*).ti,ab,kw. |
| 7 | su.fs. or (surgery or surgical or (anaesth\* or anesth\*)).ti,ab,kw. |
| 8 | exp emergency treatment/ or resuscitation/ or (emergen\* or problem\* or trauma or acute or life-threatening or complication\*).ti,ab,kw. |

**Study records:**

Data management: Describe the mechanism(s) that will be used to manage records and data throughout the review.

Selection process: Two review authors (LK, DJ) independently screened the titles and abstracts of all reports identified by electronic and manual searching on eligibility (see eligibility criteria). Articles that were evidently irrelevant were excluded at this stage. We retrieved and evaluated all potentially relevant studies, chosen by at least one review author, in full-text versions. Two review authors (LK, DJ) independently screened the full papers, identified relevant studies and assessed eligibility of studies for inclusion. This was done on a data coding sheet. Reference lists of relevant studies were cross-referenced to identify additional studies.

Data collection process: Data will be extracted with a data coding sheet, this will be done in duplicate by LK and DJ. We will contact the authors of the original studies in case additional information is required.

Data items: Data will be sought for all PICO items, Patient or model (weight, age, type), Type of surgical intervention and outcomes as described below. Funding sources will be collected if relevant (i.e. industry supported studies),

**Outcomes and prioritization:**

Primary outcomes:

* time to tracheal access (defined as visual confirmation or presence of end tidal CO2) and/or
* time to reported effective oxygenation or ventilation
* Success rate

Secondary outcomes:

* Complications
* Perceived ease of use of the technique

Primary outcomes are chosen as they represent the most important outcomes in order to compare an emergency surgical airway technique. Secondary outcomes are complications, although this is very important, actual success of the procedure and the timeframe wherein success is achieved are more important in a life threathening CICO than complications. Perceived ease of use is again important to make a decision on which technique to use, however this is subjective and will improve for all techniques with regular training.

**Risk of bias in individual studies:**

Both review authors (LK, DJ) will independently assess risk of bias in the included studies using “The Cochrane Collaboration's 'Risk of bias' tool” outlined in Table 8.5c of the Cochrane Handbook for Systematic Reviews of Interventions.2 The results of the risk of bias assessments of the included studies can be found in table 2. Blinding was not appropriate due to the nature of the intervention so this is not considered an insurmountable criteria. We initially used the Newcastle Ottowa scale3 to assess the however after the publication of the ROBINS-I4 tool for assessing the quality of the nonrandomised studies we amended this to our protocol.

Data synthesis: We plan to report the data as a SWOT-analysis to evaluate the strengths (S), weaknesses (W), opportunities (O) and threats (T) of the different surgical airway techniques in children as a pilot search revealed . the absence of high quality evidence. Quantitative synthesis will therefore be non-applicable. We plan to summarise data reported as medians and interquartile ranges by the method proposed by Wu et al.5 The strength of the body of evidence will be assessed via the GRADE approach.6

**References**

1. Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647
2. Higgins JPT, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD et al. The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials BMJ2011; 343 :d5928
3. Newcastle Ottowa scale as per Higgins JPT, Green S (eds). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011.
4. Sterne Jonathan AC, Hernán Miguel A, Reeves Barnaby C, Savović Jelena, Berkman Nancy D, Viswanathan Meera et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions BMJ 2016; 355 :i4919
5. Wan X, Wang W, Liu J, Tong T. Estimating the sample mean and standard deviation from the sample size, median, range and/or interquartile range BMC Medical Research Methodology 2014, 14:135 doi:10.1186/1471-2288-14-135
6. Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, Schünemann HJ. GRADE: an emerging consensus on rating quality of evidence and strength of recommendation. BMJ 2008; 336: 924–26

**Appendix 2. Data coding sheets**

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| **General Information** |
| Study ID (author, title, year) |
| **Study Characteristics** |
| Subjects/Models (n) | Mean age (year) and range | Mean Weight (kg) and range | Intervention  | Comparison | Operator(experience) (n) |
| **Time to tracheal access/or effective oxygenation or ventilation (seconds)** |
| Definition of outcome | How established/ documented | No. subjects having outcome | No. subjects not having outcome | N total  | Mean, SD, Median, IQR |
| **Successrate (n)** |
| Definition of outcome | How established/ documented | No. subjects having outcome | No. subjects not having outcome | N total  | %total, RR, 95% CI, p-value |
| **Complications** |
| Definition of outcome  | How established/ documented | No. subjects having outcome | No. subjects not having outcome | N total  | % totalRR, 95% CI, p-value |
| **Perceived ease of use**  |
| Definition of outcome | How established/ which instrument used | No. subjects interviewed/ provided scores | Which technique evaluated | N total | Mean Difference, 95% CI, p-value |
| **Risk of Bias RCT (Cochrane collaboration tool for assessing risk of bias)1** |
| Random sequence generation  | Allocation concealment | Blinding of participants and personnel | Blinding of outcome assessment | Incomplete outcome data | Selective reporting | Other sources of Bias |
| **Risk of Bias non-RCT (ROBINS-I)2** |
| Bias due to confounding | Bias due to participant selection | Bias in intervention classification | Bias due to deviations from intended interventions | Bias due to missing data | Bias in outcome measure- ment  | Bias in selection reported result |

1. Higgins JPT, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD et al. The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials BMJ2011; 343 :d5928
2. Sterne Jonathan AC, Hernán Miguel A, Reeves Barnaby C, Savović Jelena, Berkman Nancy D, Viswanathan Meera et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions BMJ 2016; 355 :i4919